

REMARKS

The paper is in response to the Office Action mailed January 7, 2010 ("the Office Action"). The foregoing amendment cancels claims 1-27; amends claims 28, 47-49, 51 and 55. As such, Claims 28-55 are now pending in view of the amendments. Applicants respectfully request reconsideration of the application in view of the above amendments to the claims and the following remarks. For Examiner's convenience and reference, Applicants present remarks in the order that the Office Action raises the corresponding issues.

In connection with the prosecution of this case and any related cases, Applicants have, and/or may, discuss various aspects of the disclosure of the cited references as those references are then understood by the Applicants. Because such discussion could reflect an incomplete or incorrect understanding of one or more of the references, the position of the Applicants with respect to a reference is not necessarily fixed or irrevocable. Applicants thus hereby reserve the right, both during and after prosecution of this case, to modify the views expressed with regard to any reference.

Please note that Applicants do not intend the following remarks to be an exhaustive enumeration of the distinctions between any cited references and the claims. Rather, Applicants present the distinctions below solely by way of example to illustrate some of the differences between the claims and the cited references. Finally, Applicants request that Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of any reference is consistent with Examiner's understanding.

Unless otherwise explicitly stated, the term "Applicants" is used herein generically and may refer to a single inventor, a set of inventors, an appropriate assignee, or any other entity or person with authority to prosecute this application.

Examiner's Interview

Applicants thank Examiner for the telephone interview of March 17, 2010. Claims 28, 47-49, 51, and 55 were discussed with regard to proposed amendments. References Whalen, Greff, Halimann, Lunel, and Vernon were also discussed with regard to the combination being

improper, which Examiner appears to agree with. The amendments and remarks herein reflect the substance of the interview.

Rejection Under 35 U.S.C. §112, ¶2

The Office Action rejects claim 47-49, 51, and 52 under 35 U.S.C. §112, ¶2. In response, Applicants amend claims 47-49, 51, and 55 in order to comply with the requirements of 35 U.S.C. §112, ¶2, and withdrawal of these rejections is respectfully requested.

Rejection under 35 U.S.C §103(a)

The Office action rejects claims 28-55 under 35 U.S.C §103(a) over Whalen (U.S. Patent No.6,645,167) in view of Greff et al. (U.S. Patent No. 5,667,767) and Haldimann (U.S. 6,428,576) and Verduyn Lunel ("Significance of annulus fibrosus of heart in relation to AV conduction and ventricular activation in cases of Wilff-Parkinson-White Syndrome," *British Heart Journal*, 1972, 34, 1263-1271) and Vernon et al. ("Water-borne, in situ cross-linked biomaterials from phase-segregated precursors, *J. Biomed. Material Res.*, Mar 1 2003, 64(3), pp 447-456).

In accordance with Applicants' understanding, both Whalen and Greff teach fully polymerized or cross-linked compositions that are stable, and such full compositions are administered to a blood vessel for embolization. These polymers do not react with each other, and do not result in a nucleophilic component reacting with a component containing an unsaturated bond within a blood vessel. In part, Whalen and Greff do not teach administering to a blood vessel a composition having "a nucleophilic component reacting with a component containing an unsaturated bond."

In accordance with Applicants' understanding, both Haldimann and Vernon teach compositions that can polymerize and cross-link within an annulus fibrosis disci intervertebralis, which is associated with an intervertebral disk. Haldimann and Vernon teach applying a composition having a nucleophilic component reacting with a component containing an unsaturated bond into a defect of the annulus fibrosis disci intervertebralis. As a note, a defect in the annulus fibrosis disci intervertebralis is commonly referred to as a herniated disc and is associated with back pain. As such, Haldimann and Vernon teach polymerizing or cross-linking

the composition in a region of the vertebra of the back, which is not anatomically, functionally, or physically comparable to a blood vessel. As such, nothing in Haldimann or Vernon relates to applying their compositions into a blood vessel.

In accordance with Applicant's understanding, Lunel is a reference regarding the annulus fibrosis cordi, which is a fibrous ring surrounding the atrioventricular and arterial orifices and for attachment of the bicuspid and tricuspid valves. Nothing in Lunel relates to the annulus fibrosis disci intervertebralis. The annulus fibrosis disci intervertebralis and annulus fibrosis cordi are completely different anatomical parts in unrelated parts of the body with completely different functions. Moreover, the annulus fibrosis cordi is not related to the anatomy of a blood vessel as blood vessels have completely different anatomy and physical function compared to the fibrous ring connecting the heart valves.

Applicants respectfully traverse this rejection for at least the reason that the Office Action fails to present a *prima facie* case that claims 28-55 are obvious. Under the guidelines in the MPEP, Examiner must establish that the references teach or suggest each and every claim element or explain "why the difference(s) between the prior art and the claimed invention would have been obvious".¹ The Office Action does neither. None of the references of the combination of references teaches or suggests that a composition having "a nucleophilic component and a component containing a conjugated unsaturated bond" can be crosslinked within a blood vessel "to form a crosslinked emboli and occlude the blood vessel," as recited in claim 1. None of these references teach or suggest performing such a crosslinking within a vessel to form a crosslinked emboli, and thereby the combination of references do not teach such a crosslinking within a vessel. Since the combination of references does not teach crosslinking within a blood vessel to form an emboli, the combination of references fails to teach each and every element of the presently pending claims.

¹ MPEP §2143.03 ("All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).")

MPEP §2141.III ("The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, *Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art.*" emphasis added).

While Whalen and Greff teach embolizing blood vessels with preformed polymers, these references do not teach or suggest that a cross-linking reaction can be performed in a blood vessel to form a crosslinked embodli. On the other hand, Haldimann and Vernon teach applying the composition to a defect in a vertebra disk so that crosslinking occurs at the defect, but do not teach or suggest that such a crosslinking composition can be applied to an anatomy such as a blood vessel. Due to the significant differences between an annulus fibrosis disci intervertebralis and a blood vessel, it is not obvious that the composition of Haldimann and Vernon can be applied to a blood vessel for crosslinking within the blood vessel to form an emboli, and there is no reasonable expectation of success that the compositions of Haldimann and Vernon could be useful to embolize a blood vessel under Whalen and Greff. Additionally, due to the significant differences between preformed polymers and a composition having a nucleophilic component and a component containing a conjugated unsaturated bond that reacts to form a crosslinked embodi, it is not obvious that a crosslinkable composition can be applied into a blood vessel for crosslinking within the vessel, and there is no reasonable expectation of successfully obtaining an emboli from the compositions of Haldimann and Vernon.

Additionally, the Office Action does not establish that is would be obvious to apply a composition having "a nucleophilic component and a component containing a conjugated unsaturated bond" to a blood vessel for crosslinking into a crosslinked emboli. Because the Office Action neither shows that the combination of references teach or suggest each and every claim element of claims 28-55 nor explains why the differences between the prior art and the claimed invention would have been obvious to a person of skill in the art, the Office Action fails to present a *prima facie* case that claims 28-55 are obvious and the rejection is thus improper. Applicants therefore respectfully request that Examiner withdraw the rejection of claims 28-55 under 35 U.S.C. §103(a).

Additionally, Applicants respectfully traverse this rejection for at least the reason that the rejection improperly relies on a nonanalogous reference. According to MPEP §2141.01(a).I, "a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deal, logically would have commended itself to an inventor's attention in considering his or her invention as a whole." Applicant respectfully assert that the Lunel reference is non-analogous art because it relates to the annulus fibrosis

cordi, which is unrelated to embolizing blood vessels with polymers and unrelated to the annulus fibrosis disci intervertebralis. Because the Office Action relies on a nonanalogous reference, the rejection of claims 28-55 is improper. Applicants therefore respectfully request that Examiner withdraw the rejection of claims 28-55 under 35 U.S.C. §103(a).

Charge Authorization

The Commissioner is hereby authorized to charge payment of any of the following fees that may be applicable to this communication, or credit any overpayment, to Deposit Account No. 23-3178: (1) any filing fees required under 37 CFR § 1.16; (2) any patent application and reexamination processing fees under 37 CFR § 1.17; and/or (3) any post issuance fees under 37 CFR § 1.20. In addition, if any additional extension of time is required, which has not otherwise been requested, please consider this a petition therefor and charge any additional fees that may be required to Deposit Account No. 23-3178.

CONCLUSION

In view of the foregoing, Applicants submit that the pending claims are allowable. In the event that Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview or overcome by an Examiner's Amendment, Examiner is requested to contact the undersigned attorney.

Dated this 1st day of April, 2010.

Respectfully submitted,

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